DETAILED ACTION

1. Applicant's arguments in the reply filed on 4/7/2011 are acknowledged and entered into the record.

2. An interview was held on 5/18/2011 with Attorney Leslye Davidson a summary of which is attached to the following office action.

3. Claims 29-32, 34, 36 and 37 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. The rejection of Claims 29-32, 34, 36-37 under 35 U.S.C. 103(a) as being unpatentable over Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006) in view of Ruben et al. (US Patent 7169565) are maintained for the reasons of record.

7. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody recognizing C20orf102 protein in a blood, serum, or plasma sample from a subject. The C20orf102 protein is described in the specification as amino acid sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).

8. Yue et al. teach a method of diagnosing cell proliferative disorders (e.g. cancers) by detecting nucleic acid and amino acid sequences of secreted proteins. Yue et al. disclose "the invention is based on the discovery of new human secreted proteins (SECP), the polynucleotides encoding SECP, and the use of these compositions for the diagnosis, treatment or prevention of cell proliferative, autoimmune/inflammatory, cardiovascular, neurological, and developmental disorders" (see p. 31, lines 28-31). Yue et al. disclose the gene sequence for C20orf102 (SEQ ID NO:2 of the instant application) and the amino acid sequence for C20orf102 protein (SEQ ID NO:66 of the instant application) (see previously attached alignment mailed 11/19/2008). Claim 30 of Yue et al. teach a diagnostic assay comprising combining a biological sample with an antibody which specifically binds to a SECP polypeptide and detecting the complex, wherein the presence of the complex correlates with the presence of the SECP polypeptide in the biological sample (see also p. 59, lines 5-6). Yue et al. disclose "sequences encoding SECP may be used for the diagnosis of disorders associated with expression of SECP" (see p. 60 lines 10-11). Yue et al. disclose several cancers including liver, lung, and pancreas (see p. 60-61). Yue et al. does disclose the term

"sample" is used in its "broadest sense" and can comprise a bodily fluid (see p. 29, lines 26-29), however Yue et al. does not specifically disclose a sample comprising blood, serum or plasma. This deficiency is made up for by Ruben et al.

9. Ruben et al. teach a method of identifying polypeptides in a biological sample for the diagnosis of diseases using antibodies directed to said polypeptide. Ruben et al. disclose detecting expression levels of said polypeptides in bodily fluids such as blood serum or plasma (see column 30, lines 48-54).

10. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method taught by Yue et al. of determining the presence of C20orf102 protein using an antibody in samples such as blood, plasma or serum from a subject as taught by Ruben et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Yue et al. and Ruben et al. because Yue et al. disclose bodily fluids can be used in the method of detecting C20orf102 protein and Ruben et al. disclose bodily fluids such as blood, plasma and serum can be used in a method to detect polypeptide levels using an antibody directed to said polypeptide. Therefore, Claims 29-37 are obvious over Yue et al. in view of Ruben et al.

Response to Arguments

11. Applicants argue that one of skill in the art would not be motivated to combine the teachings of the Yue reference with Ruben patent. Applicants argue that Yue teach a "sample" may comprise a body fluid or other exemplary samples derived from the body.

Applicants argue that Yu teach a laundry list of "samples" and one would not be motivated to select a sample of body fluid. The arguments have been considered but are not found persuasive.

12. Yue teach methods of detecting the same protein of the instant claims in biological samples including body fluids. Yue et al teach that this protein is a "human SECRETED protein, "SECP." Clearly, Yue recognize that the protein is secreted and teach body fluids are exemplary samples to be assayed. Yue does not specifically teach the body fluids of blood, serum, plasma, however the MPEP 2144.08 states: "When a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus, Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious." Examiner provided Ruben to demonstrate that body fluid samples of blood, serum and plasma are known and assays for protein detection in these samples are known and successful. Given Yue et al. teach detection of the same protein instantly claimed in biological samples and specifically suggest body fluid, and given the teaching of Ruben, there is a reasonable expectation of success for Yue to perform the detection assays for the same protein in body fluids of blood, serum, and plasma. Further, disclosure of alternative biological samples for protein detection do not teach away from using body fluids. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. The prior art's mere disclosure of more than one alternative does not constitute a

teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed (MPEP 2123).

13. Applicants argue that one of skill in the art after reading Yue would believe that SEQ ID NO:3 is anchored on the cell surface because Yue disclose assays for "SECP" activity measuring the expression of SECP on the cell surface and disclose that SEQ ID NO:3 shares 51% homology with a transmembrane protein. Applicants argue that Examiner improperly relies on the instant specification to demonstrate the identity of the protein in Yue and its properties, particularly the property of not being anchored. Applicants argue this is hindsight reasoning. The arguments have been considered but are not found persuasive.

14. Examiner properly relied upon the instant specification as evidence that the instantly claimed protein and protein of the prior art are the same in structure and function. Contrary to Applicants' arguments, Examiner did not use the instant specification to produce motivation to combine references or for a reasonable expectation of success. It is unclear on what basis Applicants are concluding the SECP protein would be limited to cell surface anchoring when it only shares 51% homology to a transmembrane protein, and when Yu clearly identify the protein as a "human SECRETED protein, "SECP." Examiner has demonstrated that the protein taught by Yue comprises the same sequence as the protein instantly claimed and therefore the protein of Yue would necessarily function the same as the instantly claimed protein. "Products of identical chemical composition cannot have mutually exclusive properties."

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Given the protein of Yue and the instant claims are identical in structure, they are expected to have the same functions, thus there is a reasonable expectation of success that Yue would be able to detect the same protein instantly claimed in body fluids. Ruben demonstrate further reasonable expectation of success for known methods of detection of protein in body fluid samples blood, protein, and plasma. The disclosure of detection assays for SECP on cell surface does not teach away from the teaching of detection assays in body fluids. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed (MPEP 2123).

15. Applicants argue that Ruben is only cited by Examiner for the disclosure of general techniques for detecting polypeptides in biological analytes and does not teach or suggest detecting polypeptides anchored on a cell surface. Therefore, there is no reason to combine the Ruben reference, which deals only with externally secreted proteins, with the cell anchored protein of Yue. The arguments have been considered but are not found persuasive.

16. Ruben et al. teach that body fluids blood, plasma, and serum are known and methods of protein detection in these body fluids are known and successful. Ruben

provides a reasonable expectation of success for known methods of detection of a known protein in known body fluid samples including blood, serum, and plasma.

17. Finally, Applicants are arguing limitations not recited in the claims. Applicants are reminded that the only active step required of claims 29-32 is: "detecting human C20orf102 protein." The claims do not require detection of the protein in serum, blood, or plasma as argued by Applicants, but rather, the claims characterize the protein as a protein being present in blood, serum, or plasma. Applicants have not argued how the protein of Yue is structurally and functionally different from the instantly claimed protein and that it would not be present in blood, serum, or plasma or not be detectable using the methods taught by Yue. With regards to claims 34, 36, and 37, it is prima facie obvious to detect the instantly claimed protein in collected blood, serum or plasma body fluids for the reasons of record.

Conclusion

18. Claims 29-32, 34, 36 and 37 are rejected.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Friday, 9:00AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MN/

/LAURA B GODDARD/
Primary Examiner, Art Unit 1642